Data Evaluation and Objective Assessment

Defining the State-of-the-Art in Biomedical Imaging Research

Jackson MS, March 2003

Hierarchy of Imaging Assessment

- Physical attributes and parameters
- Observer performance
- Diagnostic impact
- Therapeutic impact
- Health and cost outcomes
- Cost-effectiveness

Historical Perspective

- Most imaging clinical research has been:
  - Anecdotes and case series, or at most observer performance
  - Single institutional studies
  - Retrospective
  - Focused on “accuracy”
  - Variable rigor

Historical Perspective

- Imaging clinical research has been lacking in:
  - Pertinence
  - Validity
  - Reliability
  - Generalizability
- Often poor scientific basis for the use of imaging technology

Needs to Improve Research

- Involvement of multiple clinical disciplines
- Involvement of methodologists
  - Engineers and physicists
  - Statisticians
  - Epidemiologists
  - Sociometricians
  - Clinical trialists
- Sufficient sample sizes
- Broad participation of imaging specialists and subjects in multi-center trials

Considerations for Research

- Level of hierarchy addressed - and endpoints - depend on:
  - Status and availability of technology
    - New and emerging
    - Established
  - Availability of methods and instruments
  - Practical considerations

Practical Considerations

- Doing everything vs. having a successful trial
- Availability of:
  - Funds
  - Personnel
  - Technology
- Time to completion
  - Complexity of trial
  - Number of subjects
  - Dedication of PI and trial team
- Access to subjects
- Special Issues of imaging assessment

Special Issues of Imaging Trials

- Large number of technologies and iterations of technology

- Technologies being studied must be defined precisely
- Rigorous protocol requirements and quality control

Special Issues of Imaging Trials

- Measuring not just performance of technology but technology/human interaction

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- Must define population of “readers”

Special Issues of Imaging Trials

- Imaging event remote from outcome

- Choose the right endpoints
- Allow for sufficient sample size
- Consider time, cost, ability to accrue and follow subjects

Special Issues of Imaging Trials

- Must accrue subjects “upstream” from imaging

- Collaborate with other medical disciplines

Needs for the Future

1. Cultural change among radiologists
   a. Education in critical thinking
   b. Education in the value of research
   c. Desire to participate in clinical research – especially multi-center clinical trials
   d. Willingness to work across disciplines

Needs for the Future

2. Funding for:
    a. Continuing research infrastructure
    b. Training of physicians
    c. Training of methodologists
    d. Involvement of broad base of “imagers”

Needs for the Future

3. New methods:
    a. For all levels of the hierarchy
    b. To improve efficiency of clinical trials
        i. Surrogate endpoints
    c. For modeling and simulation
        i. Extrapolation from surrogate endpoints obtained from trials to health outcomes
        ii. Inform further trials
        iii. Reduced time and expense vs. trials

Needs for the Future

4. Integration of activity across the assessment hierarchy to:
   - Speed transition to clinical testing
   - Prepare for needed financing
   - Focus evaluation on critical elements
   - Improve rapidity of dissemination of valuable technologies

Needs for the Future

5. Interaction of all interested parties:
    a. Funding agencies
    b. Researchers
    c. Industry
    d. Payers
    e. Regulatory agencies